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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/512,701	02/25/00	LEONARD J	GI5229FWC-DI

EXAMINER	
MINNIFIELD,N	
ART UNIT	**PAPER NUMBER**
1645	5

HM22/0315

AMERICAN HOME PRODUCTS CORPORATION
PATENT & TRADEMARK DEPARTMENT- 2B
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DATE MAILED: 03/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/512,701	LEONARD ET AL
Examiner	**Group Art Unit**
N. M. Minnifield	1645

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *10-20* is/are pending in the applicat

Of the above, claim(s) *10-15* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *16-20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892 4 sheets

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicants' preliminary amendment filed February 25, 2000 is acknowledged and has been entered. Claims 1-9 have been canceled. New claims 24-28 have been added. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 24-28 been renumbered 16-20. Claims 10-20 are now pending in the present application.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 10-15, drawn to method of treating autoimmune condition comprising administering IL-12, classified in class 424, subclass 85.3.

II. Claims 16-20, drawn to method of treating rheumatoid arthritis comprising administering IL-12 antagonist, classified in class 424, subclass 130.1.

1. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP. § 806.04, MPEP. § 808.01). In the instant case the different inventions, methods of treatment, are distinct from one another since each have different pathological consequences and have different modes of operation as a result of the administration of different and distinct agents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Rebecca McNeill on February 22, 2001 a provisional election was made with traverse to prosecute the invention of Group II, claims 16-20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-15 have been withdrawn from further

consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

3. Applicants should update the status of all related applications on page 1, paragraph 1 of the specification.

4. Claims 16-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a method for treating rheumatoid arthritis in a human subject comprising administering to the subject IL-12 antagonist (antibody or antibody fragment immunoreactive with IL-12).

The specification teaches that interferon-gamma is implicated in the development, exacerbation and/or recurrence of numerous autoimmune conditions,

and that interferon-gamma is associated the multiple sclerosis, IDDM and rheumatoid arthritis. The examples set forth in the specification teach EAE in mice as a useful model for multiple sclerosis (p. 14). In vitro experiments are set forth on page 15. In vivo administration of IL-12 or IL-12 antagonist are set forth on pages 16 and 20. In vitro data on the effects of IL-12 on interferon-gamma are set forth on page 18. In vivo data on the effects of IL-12 with regard to IDDM are set forth on page 21.

However, the specification does not set forth any guidance, evidence or examples with regard to a method for treating rheumatoid arthritis in a human subject comprising administering to the subject IL-12 antagonist (antibody or antibody fragment immunoreactive with IL-12). The specification does not enable one of ordinary skill in the art to practice the claimed invention. Furthermore, the art teaches that anti-IL-12 has no statistically significant effect on the clinical outcome of disease, arthritis (abstract; p. 2206, Butler et al, 1999). Butler et al teach that the actions of both antibodies (anti-IL-12 and anti-TNF) were synergistic and that anti-IL-12 alone had little effect on clinical disease (p. 2209). "We have previously described ~~that~~ that anti-IL-12 can prevent development of the Th1 response towards CII thus reducing arthritis, when administered from immunization onwards. We have now found that after the onset of disease, treatment with anti-IL-12, on its own, was not capable of skewing the Th1 response to CII and lacks therapeutic effect..." (p. 2209, col. 2). In view of the teachings

in the art and the lack of guidance, evidence or examples in the specification with regard to a method for treating rheumatoid arthritis in a human subject comprising administering to the subject IL-12 antagonist (antibody or antibody fragment immunoreactive with IL-12), claimed invention the claimed invention is not enabled.

5. No claims are allowed.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

7. It is noted that the formal drawings are now required and that Applicant should comply with the objections to the drawings as set forth in Form 948 (Draftsperson's Notice) mailed with this Paper. Applicants should make sure that the figure descriptions set forth in the specification match the formal drawings that will be submitted.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is (703) 305-3394. The examiner can normally be reached on Monday-Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R. F. Smith, can be reached on (703) 308-3909. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

N. M. Minnifield

March 12, 2001

NITA MINNIFIELD
PRIMARY EXAMINER